Micronoma™

Instructions For Use
EGFR Plasma Collection Kit*

www.micronoma.com

Shipping Address
Micronoma Laboratories
6342 Ferris Sq. (1st floor)
San Diego, CA 92121

COLLECTION KIT MATERIALS:

EGFR Collection Kit contains: Kit box, Styrofoam Inner Box, FedEx Pak, FedEx Return Label, Double Pouch Sealable Biohazard Bag, Test Requisition Form (TRF), Instructions For Use (IFU), Two (2) K2 EDTA Tubes, One (1) Plasma 10 mL Collection Tube, Two (2) Ice Packs.

PLEASE FREEZE ALL ICE PACKS WHEN KIT IS RECEIVED.

SPECIMEN REQUIREMENTS:

Specimens will be submitted as collected plasma in the enclosed 10 mL collection White Top Tube.

MATERIALS PROVIDED BY CUSTOMER:

1. Signed and completed test requisition form, patient consents, Medicare ABN and other provided forms as needed.
2. Collected plasma in a 10 mL white top tube (derived from the K2 EDTA tubes(2)).
3. Front / back copy of patient insurance card.
4. Medical record with Certificate of Medical Necessity.
5. Release of PHI (needed per provider or per customer).

COLLECTION INSTRUCTIONS:

1. Follow blood draw protocol.
2. Fill (2) provided 10 mL EDTA Purple Top Tubes (Approx. 7-10mL per tube).
3. Centrifuge K2-EDTA Purple Top Tubes for 20 minutes at 1800 x g within 4-6 hours of collection.
4. Immediately transfer collected plasma in a 10 mL white top tube.
5. Specimens should be shipped same day of collection. Proceed with shipping instructions.

SHIPPING INSTRUCTIONS:

1. Complete Test Requisition Form (TRF). Prepare one Test Requisition Form for each patient.
   a. Before shipping, make a copy of the Test Requisition to retain for your records.
2. Prepare the specimen package for shipment. Specimens should be shipped same day of collection.
   a. Place the plasma collection tube into the pouch with the absorbent pad of the Biohazard bag. Ensure the pouch is sealed tightly.
   b. Place requisition form in the larger pouch of the Biohazard bag. Ensure the pouch is sealed tightly.
   c. Place 1 frozen ice pack at the bottom of the Styrofoam box.
   d. Place the Biohazard bag with the sample and requisition form on top of the ice pack.
   e. Place another frozen ice pack on top of the Biohazard bag.
   f. Place the lid on top of the Styrofoam box.
   g. Close the cardboard box.
   h. Place the kit box in the provided FedEx Pak and seal.
   i. Complete and/or apply the pre-printed FedEx label with shipping information.
   j. Place the package in the designated courier pickup location at your site.
3. If unable to ship same day, refrigerated collected plasma at 4C, and ship next day.
4. Contact Micronoma Customer Care Department to schedule sample pickup.

WARNING: Health and Safety Precautions – Specimen and containers should be properly sealed prior to shipment.

CONTACTING MICRONOMA CUSTOMER CARE:

For more information, please call 858-500-3734 from 9AM to 5PM PST, Monday to Friday, email customercare@micronoma.com, or visit our website, www.micronoma.com

SPECIMEN REJECTION CRITERIA:

Micronoma will reject specimens received and contact the customer under the following conditions:

1. Specimen label is missing or incomplete.
2. Specimen is damaged, delayed, or at ambient room temperature.
3. Collection tube is leaking
4. Insufficient plasma volume (less than 2 mL)

RESULTS:

You will receive your EGFR results within 5 business days once the patient's specimen is received.

ORDERING SUPPLIES:

To order kits, call or email us at the contact information above. Please allow 3-5 business days to receive additional specimen collection kits. The Test Requisition Form, specimen requirements and shipping instructions can also be downloaded and printed from www.micronoma.com

** Cobas® EGFR Mutation Test v2 (US-IVD) is an FDA approved real-time PCR test for the qualitative detection of defined mutations in exons 18, 19, 20 and 21 of the epidermal growth factor receptor (EGFR) gene in non-small cell lung cancer (NSCLC) patients. Defined EGFR mutations are detected using circulating-free tumor DNA (cfDNA) from plasma derived from EDTA anticoagulated peripheral whole blood. The test is indicated as a companion diagnostic to aid in selecting NSCLC patients for treatment specific targeted therapies. Micronoma is a CLIA certified laboratory that has validated and is approved to test the cobas EGFR Mutation Plasma Test v2.*